US ERA ARCHIVE DOCUMENT

Efficacy Review

Date: October 3 1996

Registration Number: 3125-455 Date Division Received: 08/07/96 Type of product: Insecticide

MRID Numbers : none

Product Manager: Dennis H. Edwards Jr.

Team: 19

Team reviewer: Portia Jenkins
Efficacy reviewer: Paul Schroeder

Product name: Premise 75

Company Name: Miles Incorporated (Bayer)

Submission Purpose: Label revision. Chemical and formulation: Imidacloprid

Premise 75 - 75% powder in soluble packets.

Before substitution of "Treated Zone" for "Barrier" is considered more information on how termites which try to pass through the treated zone are affected is needed. Many of the following questions were asked in an Agency letter dated May 22,1996. Do termites go off somewhere and die after exposure to imidacloprid? Are they disoriented? Is the active ingredient washed out of the surface layer of soil permitting the termites to pass above the zone where the toxicant remains? Do survivors avoid treated areas and rebuild their colonies to their former sizes? Are symbionts affected?

Is there a logical explanation why imidacloprid gave adequate control of termites in some studies but was less effective in other tests? Do climatic factors such as average soil temperatures and amount of precipitation affect efficacy? Where is the data generated by the USDA laboratories in Mississippi? Are there other efficacy studies which have not been submitted? Have you determined why imidacloprid gave five years control of termites in Japan but less than three years control in Mississippi? What are the effects of soil type, pH and organic matter levels in soil on termite colony survival?

Are some species of termites such as Formosan termites able to withstand higher levels of exposure to imidacloprid? Is there a rate response either giving longer control in a given situation or control of more vigorous or less sensitive species such as the Formosan termite?

The Statement " Annual retreatment of the entire structure should be unnecessary unless reinfestation or disruption of the treated zone has occurred" must be changed to "Annual retreatment of the structure is prohibited unless there is clear evidence that reinfestation or barrier disruption has occurred."

Add the following retreatment statement to the label: "Retreatment for subterranean termites can only be performed if there is clear evidence of reinfestation or disruption of the barrier due to construction, excavation, or landscaping and/or evidence of the breakdown of the termiticide barrier in the soil. These vulnerable or reinfested areas may be retreated in accordance with application techniques described in this product's labeling. The timing and type of these retreatments will vary, depending on factors such as termite pressure, soil types, soil conditions, and other factors which may reduce the effectiveness of the barrier."

EPA has determined that, for pre-construction applications, no termiticide should be used at less than the dosage and/or concentration specified on the labeling. Accordingly, add the following statement to the label of this termiticide: "PRE-CONSTRUCTION TREATMENT: DO NOT APPLY AT A LOWER DOSAGE AND/OR CONCENTRATION THAN SPECIFIED ON THIS LABEL FOR APPLICATIONS PRIOR TO INSTALLATION OF THE FINISHED GRADE."

EPA has also determined that for post-construction applications, the dosage and/or concentration of use may be less than label rates. However, states may continue to prohibit applications at less than label dosage and/or concentration if they so choose.

Pesticide Regulation (PR) Notice 96-7 was released October 1, 1996. You must comply with the instructions on this PR Notice in addition to resolving the imidacloprid issues discussed in our correspondence.